
Article:
Palacios, Alfredo orcid.org/0000-0001-7684-0880, Rodriguez Cairoli, Federico, Balan, Dario et al. (4 more authors) (2023) Budget impact analysis of the freestyle libre flash continuous glucose monitoring system® in patients with diabetes mellitus type 1 in Chile. Expert Review of Pharmacoeconomics & Outcomes Research. ISSN 1744-8379

https://doi.org/10.1080/14737167.2023.2171989

Taylor & Francis
Taylor & Francis Group

Expert Review of Pharmacoeconomics & Outcomes Research

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/ierp20

Budget impact analysis of the freestyle libre flash continuous glucose monitoring system® in patients with diabetes mellitus type 1 in Chile

Alfredo Palacios, Federico Rodriguez Cairoli, Dario Balan, Carlos Balmaceda, Federico Augustovski, Andres Pichon-Riviere & Ariel Bardach

To cite this article: Alfredo Palacios, Federico Rodriguez Cairoli, Dario Balan, Carlos Balmaceda, Federico Augustovski, Andres Pichon-Riviere & Ariel Bardach (2023): Budget impact analysis of the freestyle libre flash continuous glucose monitoring system® in patients with diabetes mellitus type 1 in Chile, Expert Review of Pharmacoeconomics & Outcomes Research, DOI: 10.1080/14737167.2023.2171989

To link to this article: https://doi.org/10.1080/14737167.2023.2171989

EXPERT REVIEW OF PHARMACOECONOMICS & OUTCOMES RESEARCH
https://doi.org/10.1080/14737167.2023.2171989

Taylor & Francis
Taylor & Francis Group

ORIGINAL RESEARCH

Budget impact analysis of the freestyle libre flash continuous glucose monitoring system® in patients with diabetes mellitus type 1 in Chile

Alfredo Palacios [a,b,c], Federico Rodriguez Cairoli [a], Dario Balan[a], Carlos Balmaceda [b,d], Federico Augustovski [a], Andres Pichon-Riviere [a] and Ariel Bardach [a]

[a]Department of Health Technology Assessment and Health Economics, Institute for Clinical Effectiveness and Health Policy (IECS), Buenos Aires, Argentina; [b]Centre for Health Economics, University of York, York, UK; [c]Department of Economics, Universidad de Buenos Aires, Buenos Aires, Argentina; [d]Unidad de Evaluación de Tecnologías Sanitarias, Centro de Investigación Clínica, Pontificia Universidad Católica de Chile, Santiago, Chile

ABSTRACT

Objective: To estimate the budget impact of covering the FreeStyle Libre Flash Continuous Glucose Monitoring System (FSL) for type 1 Diabetes Mellitus patients (T1DM), compared to self-monitoring of blood glucose (SMBG), from the perspective of public and private third-party payers in Chile.

Methods: A budget impact model was developed to estimate the cost difference between SMBG and FSL over five years. Two FSL coverage schemes were assessed. Input parameters were retrieved from the literature review and complemented by expert opinion. Healthcare costs were estimated by a micro-costing approach and reported in USD.

Results: For a public sector third-party payer, incorporating FSL implied a cost increase up to USD 0.013 per member per month (PMPM) for the fifth year under the broad coverage scheme and a net saving of 0.0001 PMPM (all years) under the restricted coverage scheme. From a private sector third-party payer, incorporating FSL implied savings up to USD 0.028 PMPM (fifth year) for the broad coverage scheme and up to USD 0.012 PMPM (fifth year) for the restricted scheme.

Conclusion: Incorporating the FSL for T1DM patients was associated with a marginal incremental cost for the public sector third-party payer and cost savings in Chile's private healthcare sector.

ARTICLE HISTORY
Received 18 August 2022
Accepted 19 January 2023

KEYWORDS
Budget impact analysis; Chile; cost analysis; diabetes mellitus; flash glucose monitoring; self-monitoring of blood glucose; severe hypoglycemic events

1. Introduction

Diabetes mellitus (DM) is a serious, complex, and metabolic disorder characterized by a sustained elevation of glycemia levels due to a failure to produce insulin or a decrease in the sensitivity to it [1]. According to the International Diabetes Federation (IDF) [2], in 2019 there were 463 million adults with DM globally (9.3% prevalence), and this figure is expected to increase to 700 million by the year 2045. The estimated global direct health expenditure on DM in 2019 is USD 760 billion and is expected to grow to a projected USD 825 billion by 2030 and USD 845 billion by 2045 [3]. Although there is no evidence of the economic burden of type 1 diabetes mellitus in Chile or even in the Latin American region, evidence from the United States suggests that it is considerable, reaching USD 14.4 billion each year in terms of direct medical costs and indirect costs [4].

For the case of Chile, the reported prevalence of DM increased from 4.2% in 2003 to 9.4% in 2010 and 12.3% in 2017, as reported by the National Health Survey (ENS) [5]. Particularly for type 1 diabetes mellitus, Carrasco et al. reported that the overall incidence of this disease in the metropolitan region of Santiago during the period 1986–2003 was 1.70 times more that for the years 1986–1992 (4.02 cases versus 2.36 cases per 100,000 per year, respectively) [6].

The standard treatment in patients with T1DM is the insulin replacement therapy [7]. One of the main short-term complications associated with insulins is the occurrence of hypoglycemic events. To prevent these events, and to test the effectiveness of therapy, self-monitoring of blood glucose (SMBG) is currently universally recommended as a standard of care for diabetic patients treated with insulin [8] and test strips are the most frequently used technology to perform it. An alternative is represented by continuous glucose monitoring systems (CGMS). In particular, the FreeStyle Libre Flash Continuous Glucose Monitoring System® (FSL) consists of a sensor that adheres to the skin and, through a filament inserted into the subcutaneous tissue, contacts the interstitial tissue, making continuous interstitial glucose measurements. This method has the advantage of potentially providing complete historical information, and the patients also acquire higher autonomy [9].

The efficacy and safety of the FSL in patients with T1DM was evaluated in a multicenter, prospective, non-blinded, randomized controlled trial (the IMPACT study) [10] and in

CONTACT Alfredo Palacios apalacios@iecs.org.ar Department of Health Technology Assessment and Health Economics, Institute for Clinical Effectiveness and Health Policy (IECS), Buenos Aires, Argentina, Centre for Health Economics, University of York, York, UK, Universidad de Buenos Aires, Department of Economics, Buenos Aires, Argentina

Supplemental data for this article can be accessed online at https://doi.org/10.1080/14737167.2023.2171989

a subgroup analysis of this 'parent' trial study [11]. The IMPACT study compared the CGMS to the standard of care, represented by SMBG with test strips. Among the outcomes assessed in the study, a significant decrease in hypoglycemic events was reported favoring the FSL.

Regarding the authorization and indication status, according to the current regulation scheme for medical devices in Chile, the FSL is not subject to health regulation. The device is already on sale for all patients with DM who are indicated to perform glycemic self-monitoring, both in DM1 and DM 2, from 4 years of age, with the aim of replacing capillary measurement [12].

The Chilean health system mainly comprises two health insurances: FONASA and ISAPREs. On the one hand, FONASA, the only public insurer, offers health coverage to about 70% of the Chilean population. On the other hand, ISAPREs include private health insurers that give health coverage to about 15% of higher-income individuals in Chile. The remaining population receives coverage from different insurers, such as those of the Armed Forces (about 5% of the population), commercial insurance coverage, or no coverage (both account for the rest 10%). FONASA and the ISAPREs have defined different copayments for healthcare assistance [13]. Nevertheless, the treatment of T1DM is under a financial coverage scheme through the *Garantías Explícitas en Salud* Plan (Explicit Guarantees in Health Regime, GES) or 'Plan AUGE.' [8]. The GES constitutes a health benefits package guaranteed by law for people affiliated with FONASE and ISAPRE. The price of the GES Plan depends on the individual's affiliation. While an individual affiliated with FONASA does not pay for it, a person affiliated with an ISAPRE must pay a monthly amount determined by ISAPRE [8].

Some studies have evaluated the economic impacts of FSL on healthcare systems. Three studies analyzed the direct medical costs of FSL compared to SMBG in the context of the US [14], UK [15], and Spain [16]. Some studies analyzed the cost-effectiveness of this technology for the T1DM population in Sweden [17], Scotland [18], China [19], Spain [20], Australia and European countries [21]. Flash glucose monitoring showed to be cost-effective for patients with T1DM in all these cases. A budget impact analysis for the United Kingdom T1DM population has been recently published [22]. Although this study contributes to inform healthcare coverage decisions in the UK, there is not yet a similar analysis done in Latin American countries.

Thus, the objective of this study was to develop the first independent budget impact model to estimate the budget impact of the potential inclusion of the FSL for glucose monitoring in patients with T1DM from the perspective of the public and private health system in Chile, considering two potential evidence-based coverage schemes.

2. Methods

2.1. Model description

A Budget Impact Analysis (BIA) model was designed, developed and programmed in Microsoft Excel 2010 (Microsoft, USA) to estimate the financial consequences derived from the coverage of the FSL in the public (FONASA) and private (ISAPRE) health system in Chile. The model includes the estimation of the population with T1DM that is candidate to receive FSL or test strips; the diffusion rate (market share) of the FSL concerning the test strips; the costs associated with the acquisition of technologies; the direct medical costs of the management of T1DM and the costs of health events associated with T1DM (hypoglycemia events requiring third-party assistance). The model considers a static hypothetical cohort of 100,000 covered individuals, and a time horizon of five years. The costs were measured in Chilean pesos of 2020 and expressed in United States of America dollars (USD) at the exchange rate of 1 USD = 792.73 Chilean pesos [23]. We followed the ISPOR Budget Impact Analysis Good Practice II Task Force for BIA methods as well as reporting recommendations [24]. Figure 1 presents the BIA model structure. The two potential coverage schemes defined for FSL will be described in the next subsection.

2.2. Coverage schemes and target population

Given the global variability in coverage and reimbursement policies for FSL, we defined two hypothetical evidence-based coverage schemes for T1DM patients in Chile: broad and restricted coverage schemes. For the former, we considered that all the adults (considering a population over 18 years of age) with a T1DM medical diagnosis in Chile would be eligible candidates to receive the FSL. To estimate the target population for the broad scheme, we used data from the *Estudio de Verificación de Costos* (Cost Verification Study, EVC) 2018 [25]. The EVC 2018 is an analysis carried out every three years by the Chilean Ministry of Health to estimate the average total and individual expected cost per beneficiary for each health condition included in the Explicit Guarantees in Health regime (GES), being T1DM part of it. On the other hand, concerning the target population estimation for the restricted coverage scheme, we followed a former criterion established by the National Health Service (NHS of England) for FSL in T1DM patients in the UK [26]. Until the beginning of 2022, the NHS indicated that T1DM patients candidates to receive the FSL have to meet at least one of the following conditions: undergoing intensive SMBG, more than eight measurements per day; patients who meet the NICE criteria for continuous insulin infusion pump indication or who have disabling hypoglycemia; patients who have recently debuted with inadvertent hypoglycemic episodes; patients with frequent hospitalizations (> 2 per year); and those that require a third party to carry out monitoring and it is not possible to perform blood tests [26]. Given the lack of information about the percentage of T1DM patients in Chile would meet at least one of the NICE criteria, we decided to use data published for the UK population to approximate this value. On average, 22.5% of T1DM patients in the UK (including children and adolescents) comply with these conditions [27]. We assumed that 22.5% of T1DM patients in Chile (including children and adolescents) also meet at least one of these criteria. Given that our coverage scheme considers T1DM adults, an age specific

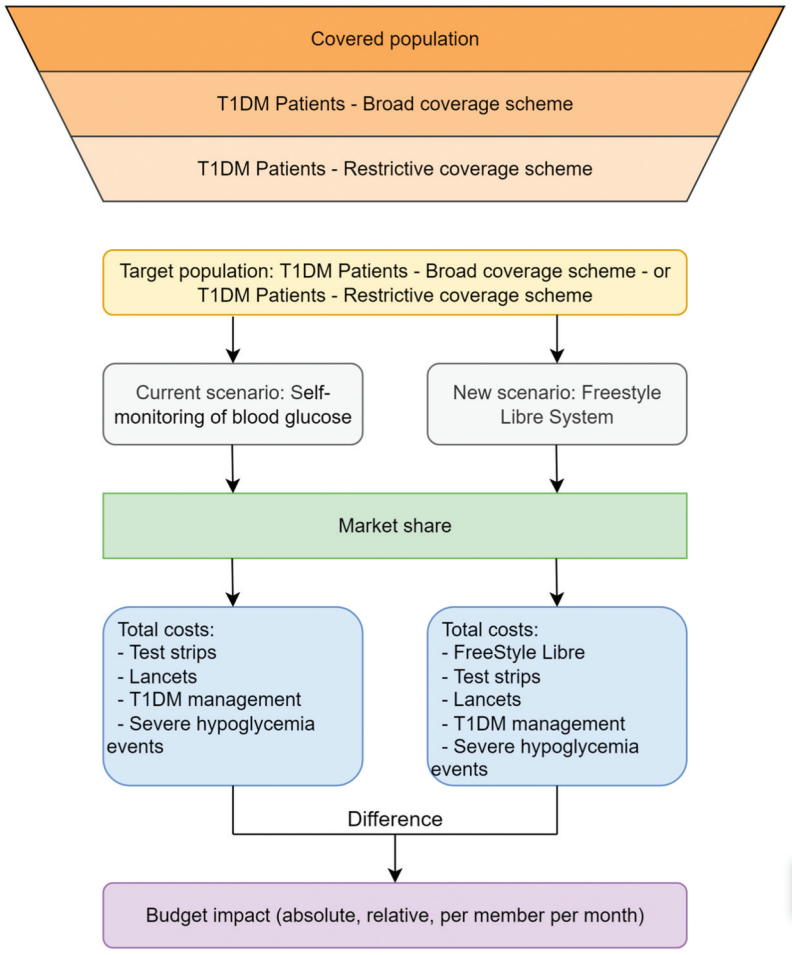

Figure 1. Analytical framework of the BIA model.

population adjustment (assuming a proportional distribution of T1DM patients matching restricted criteria among the whole population regardless of age range) was made to reflect the target population for this scheme in Chile [28].

2.3. Clinical parameters and efficacy of technologies

We identified data on efficacy of FSL from the subgroup analysis of the IMPACT study [11]. According to the information reported in the IMPACT study, we considered the percentage reduction in the number of hypoglycemic events with glycemia value below 40 mg/dl as a proxy of reduction in patient-required assistance hypoglycemic events (severe hypoglycemic event). This approach is consistent with that reported by the American Diabetes Association (ADA) [29], and it was used in a previous FSL costing study [16].

The budget impact associated with the proposed efficacy measure depends on the number of severe hypoglycemic events (SHE) at baseline in patients with T1DM in Chile, which were obtained from the HAT study [30]. Although the HAT study reports specific data for some Latin American countries, it does not include Chile in its sub-analysis. Given that Chile could differ in several aspects from other Latin American countries (for instance, Chile is the only high-income country in the region), we decided to use the average number for SHE from all the participant countries in the HAT study. We assumed that the adherence rate to monitoring for T1DM patients was 100%.

2.4. Market share

The market share, or expected diffusion rate, of the FSL regarding SMBG with test strips was estimated by the research team, composed of epidemiologists, clinicians, and health economists, with the support of a local epidemiological expert in DM. The market share rates were established to simulate the potential coverage of the FSL in the GES program coverage (involving public and private health system) for five years, consistent with the time horizon of the BIA.

2.5. Resources utilization and cost parameters

2.5.1. Broad coverage scheme

The technologies acquisition costs involve the FSL (reader and sensor), the test strips, disposable lancets and the glycemia meter. The acquisition cost of the FSL (reader and sensor) was provided by Abbott Chile, while the acquisition costs of test strips, disposable lancets and the glycemia meter were obtained from EVC 2018 [25]. To estimate the expected annual

acquisition cost per patient with SMBG with test strips, we assumed the amounts and frequencies of test strips used reported by the EVC 2018 [25]. For T1DM patients, the EVC considered an average of 4 daily measurements, that is, 1,460 test strips and 365 lancets per year. For the FSL, the daily amount of test strips were obtained from the information reported by the IMPACT study [10]. Finally, for the FSL arm, we estimated the number of lancets using the same relationship between the total number of test strips and lancets used for the SMBG population. For further details see Table 1.

The costs of the usual clinical care of T1DM were obtained from the EVC 2018 [25]. According to the opinion of the local experts, the baskets reported in the EVC 2018 [25] are representative of the health services that a patient with T1DM can access in Chile. For the hypoglycemic events, we estimated its costs by the micro costing method. The health resources and services required for its management were defined according to the specialized literature [31,32] and the opinion of local experts.

To identify the utilization of healthcare resources in SHE, we followed the methodological approach proposed by Heller et al. [33], which was used in previous economic evaluation in the field [14]. Heller et al. [33] reported that, of all the SHE that have occurred, 9.5% was resolved in the emergency room (time hospitalization of fewer than 24 hours), and 5% required time hospitalization of more than 24 hours. Also, the study identified that 31% of these events needed healthcare from an emergency team at home (ambulance). However, we did not consider the later item (ambulance) in our budget impact because in Chile this is usually paid through out-of-pocket payments.

Finally, possible costs related to the patient's training in using the FSL were not considered. According to clinical experts' opinion, the complexity of handling the device did not require any consultation or additional training for those already considered within the usual management of the disease.

Table 1. Model inputs parameters.

Input parameter	Value	Source
Epidemiology		
Prevalence of T1DM (%), public sector	0.08	MSAL 2019
Prevalence of T1DM (%), private sector	0.11	
T1DM patients with NICE criteria (%)	15.78	NICE 2017; NHS 2020
Severe hypoglycemic events (SHE) per individual per year		
No. of SHE	4.90	HAT 2016
% of SHE with emergency room, broad coverage scheme	9.50	Heller 2016
% of SHE with hospital admission, broad coverage scheme	5.00	
No. of SHE with emergency room, broad coverage scheme	0.47	Model calculation
No. of SHE with hospital admission, broad coverage scheme	0.25	
No. of SHE with emergency room, restricted coverage scheme	1.30	
No. of SHE with hospital admission, restricted coverage scheme	0.69	
Number of test strips per individual per day		
Self-monitoring of blood glucose	4.0	MSAL 2013
FSL	0.5	Bolinder 2016
Number of lancets per individual per day		
Self-monitoring of blood glucose	1.0	MSAL 2013
FSL	0.125	Assumption
Number of FSL Sensor and reader per individual per year		
Sensor	26.00	FSL Manual
Reader	0.33	
Efficacy measure		
% decrease of SHE (proxy)	58.6	Oskarsson 2017
Market share of FreeStyle Libre (%)		
Year 1	30	Own estimation
Year 2	45	
Year 3	60	
Year 4	75	
Year 5	80	
Acquisition costs (USD)*		
FSL Sensor (per unit), public sector	$ 30.60	Own estimation based on Abbott Chile
FSL Sensor (per unit), private sector	$ 26.24	
FSL Reader (per unit), public sector	$ 30.60	
FSL Reader (per unit), private sector	$ 26.24	
Test strips (per unit), public sector	$ 0.30	Own estimation based on MSAL 2019
Test strips (per unit), private sector	$ 0.48	
Lancets (per unit), public sector	$ 0.16	
Lancets (per unit), private sector	$ 0.25	
Healthcare costs (USD)*		
T1DM management per patient-year, public sector	$ 504.37	Own estimation
T1DM management per patient-year, private sector	$ 1,120.44	
SHE with emergency room, public sector	$ 157.31	
SHE with emergency room, private sector	$ 247.50	
SHE with hospital admission, public sector	$ 656.31	
SHE with hospital admission, private sector	$ 2,168.02	

Notes: *Healthcare costs consider only the payment made by the third-party payer, i.e. not include the copayments paid by the patients. Exchange rate 2020: USD 1 = $ 792.73 Chilean pesos.

2.5.2. Restricted coverage scheme

We account for the possible higher rate of health resource utilization of the T1DM target patients in this restricted scheme in comparison to the broad coverage scheme. Consequently, we decided to apply a multiplicative factor to the resource utilization percentages used in the broad coverage scheme for SHE. In order to choose the more appropriate and conservative multiplicative factor, we took into consideration one of the NICE criteria, which is reaching more than two hospitalizations per patient per year [26]. After applying a multiplicative factor of 2.80, the model estimates that each patient of this scenario will have, on average, two hospitalizations per year (including hospitalizations in the emergency room and >24 hrs. hospitalizations).

2.6. Coverages and copays

On average, the public health sector (FONASA) covers 93.3% of the total healthcare spending (the remaining 6.7% is paid by users through copayments). The private health sector (ISAPRE) covers 80% of the total healthcare spending (the rest is paid by patients through copayments) [34]. In this study, only health care costs that are paid by the third-party payer will be considered, that is, copayments paid by users will not be considered, since the latter is not included in the analysis perspective [24]. For further details about healthcare coverage and copayments see Supplementary material.

2.7. Budget impact threshold

Because Chile does not have an official guide that specifies the threshold for identifying technologies with high budgetary impact, we follow the threshold recommendations suggested by Pichon-Riviere et al. [35]. In this study, the authors estimated that the threshold of high budgetary impact for Chile is USD 190,488 per year per million inhabitants or, what is equivalent, USD 0.0158 PMPM [(USD 190,488/1,000,000)/12].

2.8. Sensitivity analysis

We conducted a deterministic sensitivity analysis to analyze the effect of modifying single key parameters on the budget impact result. The parameters considered for this analysis were the efficacy of FSL in terms of reducing the number of SHE, the acquisition cost of FSL (sensor plus reader), the acquisition cost of the SMBG with test strips, and the cost per each severe hypoglycemic event. For the FSL efficacy values and for the acquisition costs and healthcare costs we considered a variability range of ± 25% to the central values, as suggested by the economic evaluation literature [36,37]. Although Oskarsson et al. [11] do not report variability around the central efficacy value for reduction of hypoglycemic events with values less than 40 mg/dl, the arbitrary uncertainty values of ± 25% that we considered are in line with the variability reported for other efficacy values in this study (for example, for the value of efficacy in reducing hypoglycemic events with values less than 45 mg/dl).

2.9. Scenario analyses

2.9.1. Number of test strips per patient per day

Given the variability that could exist in using test strips by T1DM patients in SMBG (and its consequent effect on the budgetary impact results of covering FSL), we developed a scenario analysis that presents the budget impact results to different frequency use in test strips by patients in SMBG. The number of test strips considered in this analysis ranged from lower values than the base case value (4 test strips per day) to 10 test strips per day depending on the clinical context, according to international clinical guidelines [38,39].

2.9.2. Alternative Market Shares

Given the uncertainty in the prospective FSL market share in Chile, we conducted a scenario analysis using different market-share values representing a 'slow uptake' FSL scenario and a scenario considering a 'rapid uptake' for this technology. For the 'slow uptake' scenario, market-share values were 10% lower, as absolute values, than those used in the base case, for each year. On the other hand, for the 'rapid uptake' scenario we used market-share values 10% greater (absolute value) than those used in the base case, for each year. In addition, we conducted a 'pessimistic' scenario for the third-party payer assuming a market share of 100% for the FSL for each year of analysis.

3. Results

3.1. Input parameters

Table 1 presents the values and sources of the main epidemiological, efficacy, market-share and cost parameters for the BIA model. For information about the rest of the parameters used in the model see Supplementary material.

3.2. Target population

Table 2 shows the estimation of the target population, and its distribution between technologies through the five budget years, for the public and private perspectives and for the broad and restricted coverage schemes. For the public sector, considering a hypothetical cohort of 100,000 covered individuals, we estimated a target population of 81 individuals for the broad coverage scheme and 13 individuals for the restricted coverage scheme. For the private sector, we estimated a target population of 110 individuals for the broad scheme and a target population of 17 individuals for the restricted coverage scheme. According to the estimations of the market share of FSL, it is expected that after the inclusion of the technology in the GES program, 30% of the target population will use FSL in year 1, with this percentage increasing to 80% in the year 5.

3.3. Cost per patient per year by technology

Table 3 shows the costs per patient per year by technology, for the broad and restricted coverage schemes, and for the public and private perspectives. For both coverage schemes and perspectives, FSL was associated with an incremental

Table 2. Target population and its distribution between technologies. Hypothetical cohort of 100,000 covered individuals.

			Year				
Perspective	Coverage scheme	Technology	1	2	3	4	5
Public sector	Broad	*Target population*	81	81	81	81	81
		FSL	24	36	49	61	65
		Test strips	57	45	32	20	16
	Restricted	*Target population*	13	13	13	13	13
		FSL	4	6	8	10	10
		Test strips	9	7	5	3	3
Private sector	Broad	*Target population*	110	110	110	110	110
		FSL	33	50	66	83	88
		Test strips	77	61	44	28	22
	Restricted	*Target population*	17	17	17	17	17
		FSL	5	8	10	13	14
		Test strips	12	10	7	4	3

Table 3. Cost per patient per year by technology. In USD dollars of 2020.

Concept	FSL (A)	SMBG (B)	Difference (A) – (B)
T1DM Broad coverage scheme			
Perspective: public sector			
Management of T1DM	$504.37	$504.37	$0.00
Test Strips	$54.75	$438.00	-$383.25
Lancets	$7.52	$60.14	-$52.62
FSL (Sensor + Reader)	$805.71	$0.00	$805.71
SHE with emergency room	$30.32	$73.23	-$42.91
SHE with hospital admission	$66.57	$160.80	-$94.23
Total	$1,469.23	$1,236.53	$232.70
Perspective: private sector			
Management of T1DM	$1,120.44	$1,120.44	$0.00
Test Strips	$87.67	$701.33	-$613.67
Lancets	$11.60	$92.82	-$81.22
FSL (Sensor + Reader)	$690.86	$0.00	$690.86
SHE with emergency room	$47.70	$115.21	-$67.51
SHE with hospital admission	$219.90	$531.17	-$311.26
Total	$2,178.16	$2,560.97	-$382.80
T1DM Restricted coverage scheme			
Perspective: public sector			
Management of T1DM	$504.37	$504.37	$0.00
Test Strips	$54.75	$438.00	-$383.25
Lancets	$7.52	$60.14	-$52.62
FSL (Sensor + Reader)	$805.71	$0.00	$805.71
SHE with emergency room	$84.88	$205.03	-$120.15
SHE with hospital admission	$186.40	$450.23	-$263.84
Total	$1,643.63	$1,657.77	-$14.15
Perspective: private sector			
Management of T1DM	$1,120.44	$1,120.44	$0.00
Test Strips	$87.67	$701.33	-$613.67
Lancets	$11.60	$92.82	-$81.22
FSL (Sensor + Reader)	$690.86	$0.00	$690.86
SHE with emergency room	$133.55	$322.59	-$189.03
SHE with hospital admission	$615.73	$1,487.26	-$871.54
Total	$2,659.84	$3,724.44	-$1,064.60

Notes: *Acquisition costs and healthcare costs consider only the payment made by the third-party payer, i.e. not include the copayments paid by the patients. Exchange rate 2020: USD 1 = $ 792.73 Chilean pesos.

acquisition cost of FSL Sensor and Reader, and with financial savings in acquisition costs of test trips and lancets, and for SHE. For the public sector, FSL represented an incremental cost of USD 230.84 per patient-year for the broad coverage scheme and a net saving of USD 388.08 for the restricted coverage scheme. For the private sector, FSL represented a net saving per patient-year of USD 23.67 for the broad coverage scheme and USD 1091.60 for the restricted coverage scheme.

3.4. Budget impact

Table 4 shows, for the T1DM broad coverage scheme, the total expenditure for the current scenario (without the implementation of the FSL), the new scenario (inclusion of the FSL), and the budget impact (difference in expenditure between the current and the new scenario) in absolute, relative and per member per month (PMPM) measures, for the public and private health system perspectives. For both perspectives, the FSL coverage was associated with an incremental

Table 4. Budget impact results. T1DM Broad coverage scheme. Base case. Hypothetical cohort of 100,000 covered individuals. In USD dollars of 2020.

		Year					
Perspective	Concept	1	2	3	4	5	Cumulative
Public sector	Current scenario, total expenditure	$100,159	$100,159	$100,159	$100,159	$100,159	$500,796
	New scenario, total expenditure	$105,814	$108,641	$111,468	$114,296	$115,238	$555,458
	Budget impact, absolute	$5,655	$8,482	$11,309	$14,137	$15,079	$54,662
	Management of T1DM	$0	$0	$0	$0	$0	$0
	Test strips	-$9,313	-$13,969	-$18,626	-$23,282	-$24,835	-$90,025
	Lancets	-$1,279	-$1,918	-$2,558	-$3,197	-$3,410	-$12,361
	FSL (Sensor + Reader)	$19,579	$29,368	$39,158	$48,947	$52,210	$189,262
	SHE with emergency room	-$1,043	-$1,564	-$2,085	-$2,607	-$2,781	-$10,080
	SHE with hospital admission	-$2,290	-$3,435	-$4,579	-$5,724	-$6,106	-$22,134
	Budget impact, relative (%)	5.6%	8.5%	11.3%	14.1%	15.1%	10.9%
	Budget impact, PMPM	**0.005**	**0.007**	**0.009**	**0.012**	**0.013**	**0.009**
Private sector	Current scenario, total expenditure	$281,707	$281,707	$281,707	$281,707	$281,707	$1,408,533
	New scenario, total expenditure	$269,074	$262,758	$256,441	$250,125	$248,020	$1,286,418
	Budget impact, absolute	-$12,633	-$18,949	-$25,265	-$31,581	-$33,687	-$122,115
	Management of T1DM	$0	$0	$0	$0	$0	$0
	Test strips	-$20,251	-$30,377	-$40,502	-$50,628	-$54,003	-$195,760
	Lancets	-$2,680	-$4,020	-$5,361	-$6,701	-$7,147	-$25,909
	FSL (Sensor + Reader)	$22,798	$34,197	$45,597	$56,996	$60,796	$220,384
	SHE with emergency room	-$2,228	-$3,342	-$4,456	-$5,570	-$5,941	-$21,536
	SHE with hospital admission	-$10,272	-$15,408	-$20,543	-$25,679	-$27,391	-$99,293
	Budget impact, relative (%)	−4.5%	−6.7%	−9.0%	−11.2%	−12.0%	−8.7%
	Budget impact, PMPM	**(0.011)**	**(0.016)**	**(0.021)**	**(0.026)**	**(0.028)**	**(0.020)**

Notes: *Acquisition costs and healthcare costs consider only the payment made by the third-party payer, i.e. not include the copayments paid by the patients. Exchange rate 2020: USD 1 = $ 792.73 Chilean pesos.

acquisition cost of FSL Sensor and Reader, and with financial savings in acquisition costs of test trips and lancets, and SHE.

For the T1DM broad coverage scheme, the budget impact results for FSL coverage depended on the perspective of the analysis. For the public sector, the FSL coverage was associated with an absolute budget impact (incremental cost) of USD 5,655 per 100,000 individuals in the first year to USD 15,079 in the fifth year, with a cumulative absolute budget impact of USD 54,662. This represents a relative budget impact of 5.6% in the first year to 15.1% in the fifth year, and a budget impact PMPM of USD 0.005 in the first year to USD 0.013 in the fifth year. On the other hand, for the private sector, the FSL coverage was associated with an absolute net saving of USD 12,633 in the first year to USD 33,687 in the fifth year, with a cumulative absolute net saving of USD 122,115. This represents a relative saving of 4.5% in the first year to 12% in the fifth year, and a net saving PMPM of USD 0.011 in the first year to USD 0.028 in the fifth year.

For the T1DM restricted coverage scheme, Table 5 shows that for the public sector, the FSL coverage was associated with an absolute net saving of USD 54 in the first year to USD 145 in the fifth year, with a cumulative absolute net saving of USD 524. This represents a relative net saving of 0.3% in the first year to 0.7% in the fifth year, and a net saving PMPM of

Table 5. Budget impact results. T1DM Restricted coverage scheme. Base case. Hypothetical cohort of 100,000 covered individuals. In USD dollars of 2020.

		Year					
Perspective	Concept	1	2	3	4	5	Cumulative
Public sector	Current scenario, total expenditure	$21,188	$21,188	$21,188	$21,188	$21,188	$105,940
	New scenario, total expenditure	$21,134	$21,107	$21,080	$21,052	$21,043	$105,416
	Budget impact, absolute	-$54	-$81	-$108	-$136	-$145	-$524
	Management of T1DM	$0	$0	$0	$0	$0	$0
	Test Strips	-$1,469	-$2,204	-$2,939	-$3,674	-$3,919	-$14,205
	Lancets	-$202	-$303	-$404	-$504	-$538	-$1,951
	FSL (Sensor + Reader)	$3,089	$4,634	$6,179	$7,723	$8,238	$29,864
	SHE with emergency room	-$461	-$691	-$921	-$1,152	-$1,229	-$4,453
	SHE with hospital admission	-$1,012	-$1,517	-$2,023	-$2,529	-$2,698	-$9,779
	Budget impact, relative (%)	−0.3%	−0.4%	−0.5%	−0.6%	−0.7%	−0.5%
	Budget impact, PMPM	(0.0000)	(0.0001)	(0.0001)	(0.0001)	(0.0001)	(0.0001)
Private sector	Current scenario, total expenditure	$64,645	$64,645	$64,645	$64,645	$64,645	$323,224
	New scenario, total expenditure	$59,101	$56,330	$53,558	$50,786	$49,862	$269,637
	Budget impact, absolute	-$5,543	-$8,315	-$11,087	-$13,859	-$14,783	-$53,587
	Management of T1DM	$0	$0	$0	$0	$0	$0
	Test Strips	-$3,195	-$4,793	-$6,391	-$7,989	-$8,521	-$30,889
	Lancets	-$423	-$634	-$846	-$1,057	-$1,128	-$4,088
	FSL (Sensor + Reader)	$3,597	$5,396	$7,195	$8,993	$9,593	$34,774
	SHE with emergency room	-$984	-$1,476	-$1,969	-$2,461	-$2,625	-$9,515
	SHE with hospital admission	-$4,538	-$6,807	-$9,076	-$11,345	-$12,102	-$43,869
	Budget impact, relative (%)	−8.6%	−12.9%	−17.2%	−21.4%	−22.9%	−16.6%
	Budget impact, PMPM	(0.005)	(0.007)	(0.009)	(0.012)	(0.012)	(0.009)

Notes: *Acquisition costs and healthcare costs consider only the payment made by the third-party payer, i.e. not include the copayments paid by the patients. Exchange rate 2020: USD 1 = $ 792.73 Chilean pesos.

USD 0.0001 in the fifth year. On the other hand, for the private sector, the FSL coverage was associated with an absolute net saving of USD 5,543 in the first year to USD 14,783 in the fifth year, with a cumulative absolute net saving of USD 53,587. This represents a relative saving of 8.6% in the first year to 22.9% in the fifth year, and a net saving PMPM of USD 0.005 in the first year to USD 0.012 in the fifth year.

3.5. Sensitivity analysis

Figure 2 shows that for the broad coverage scheme the budget impact results were more sensitive to the variation in the acquisition costs of the technologies (FSL and test strips). In the case of the public sector (Panel A), the individual variation of each parameter did not imply financial savings derived from the coverage of the FSL. In the case of the private sector (Panel B), the individual variation of each parameter did not imply an incremental cost associated with the coverage of the FSL. For the case of the restricted coverage scheme from the public perspective (Panel C), the variation of each parameter implies an incremental cost or saving associated with the FSL coverage. Finally, from the private perspective (Panel D), the FSL efficacy and the weighted average cost of SHE per patient/year were the most influential parameters on the budget impact result. However, the individual variation of each parameter did not imply an incremental cost associated with the FSL coverage.

3.6. Scenario analysis

Figures S1 to S4 (see Supplementary Material) show the results of the scenario analysis for the budget impact PMPM of the coverage of FSL against a different number of test strips used by patients in SMBG. Figure S1 (see Supplementary Material) shows that from the public sector perspective the budget impact of FSL coverage exceeds the high budget impact threshold when patients use three or fewer test strips per day. In the case of the private sector under the broad coverage scheme (Figure S2, please see Supplementary Material) and from public and private sector third-party payer under the restricted coverage scheme (Figures S3 and S4, please see Supplementary Material) the threshold of high budgetary impact is not achieved.

On the other hand, Tables S3 to S8 (see Supplementary Material) show the budget impact results for the FSL market share scenarios 'slow uptake,' 'rapid uptake' and '100% uptake.' In all these scenarios, the budget impact results of FSL continues being cost saving for the public and private third-party payers in the restricted coverage scheme, and for the private third-party payer in the broad coverage scheme. For the case of the public third-party payer perspective for the broad coverage scheme, the budget impact analysis never crosses the high budget impact threshold in any of the scenarios considered.

4. Discussion

The present study aimed to estimate the budget impact of the FSL incorporation for patients with T1DM in Chile from the perspectives of the public as well as the private healthcare sector. In the absence of local coverage policies for this technology, two hypothetical schemes were defined: a broad and a restricted coverage scheme. Our results suggest that FSL coverage could be associated with financial savings or a cost increase for the third-party payer depending on the perspective of analysis. For the case of the public sector perspective, the FSL coverage was associated with a cost increase that ranged from USD 0.005 PMPM (first year) to USD 0.013 PMPM (fifth year) for the broad coverage scheme, and from USD 0 PMPM (first year) to a net saving of USD 0.0001 PMPM (fifth year) for the restricted coverage scheme. From the private healthcare perspective, the FSL coverage was associated with financial savings that ranged from USD 0.011 PMPM (first year) to USD 0.028 PMPM (fifth year) for the broad coverage scheme, and from USD 0.005 PMPM (first year) to USD 0.012 PMPM (fifth year) for the restricted coverage scheme. Following the high budget impact threshold recommendations by Pichon-Riviere et al. [35], we identified that for both

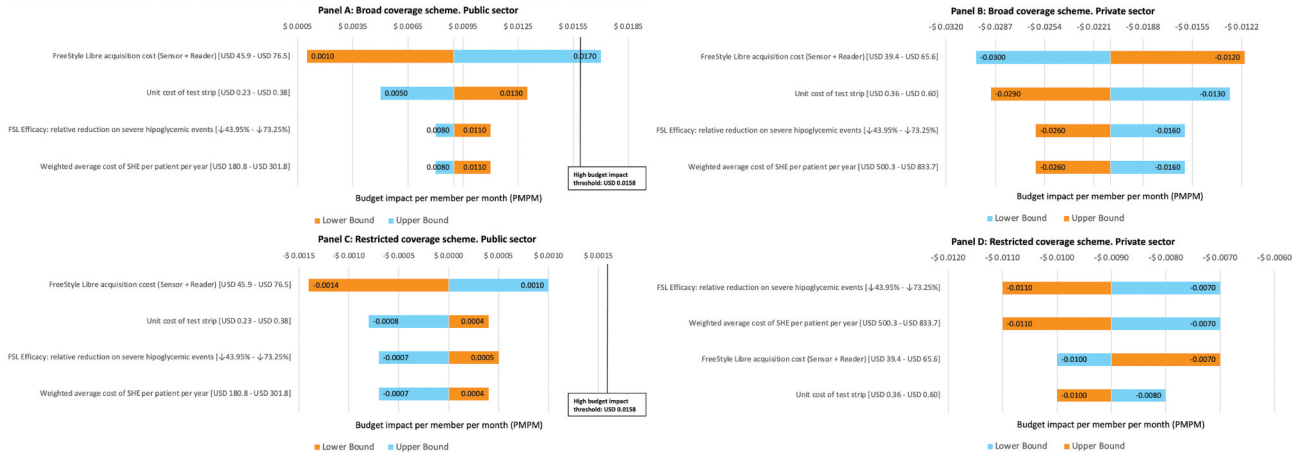

Figure 2. Deterministic sensitivity analysis. Budget impact per member per month (PMPM) values expressed in USD dollars of 2020 for both coverage schemes and healthcare perspectives (panels A, B, C, and D). High budget impact threshold value: USD 0.0158 PMPM.

Notes: FSL: FreeStyle Libre Flash Continuous Glucose Monitoring System®. Exchange rate 2020: USD 1 = $ 792.73 Chilean pesos.

perspectives and the broad and restricted coverage schemes, the coverage of the FSL would not be associated with a high budgetary impact in none of the five years of analysis.

Our study's results align with other studies analyzing the costs of FSL in high-income countries. In the United States, Shi et al. [14] estimated the costs associated with FSL as a replacement for SMBG for patients with T1DM and T2DM using intensive insulin from the private sector's perspective. For the base case (SMBG at 8 tests/day), the annual cost of SMBG was USD 4,380 for a patient with T1DM, compared with USD 1,712 for flash monitoring, a reduction of USD 2,667 (61%). In a similar costing study from the perspective of the UK National Health Service (NHS), Hellmund et al. [15] estimated that the annual direct medical costs per each T1DM patient using FSL was about 20% lower compared with routine SMBG (assuming use of 10 tests per day). Finally, Blissett et al. [22] have reported the budget impact results of the FSL adoption for the UK T1DM population. The authors concluded that adopting the FSL in T1DM showed clinical benefits and a relatively small budget impact compared with the total cost of glucose management [22]. Complementary to our analysis, the authors considered the improvement of glycated hemoglobin (HbA1c) associated with FSL in this population.

The study has strengths. First of all, the research team developed a budget impact model that considers the main characteristics of the local healthcare system and clinical practice regarding the management of T1DM and the use of the technologies under study. Second, the budget impact model considered two potential coverage schemes for using the FSL, providing comprehensive information for the third-party payer from the public and private perspectives. Third, all health event costs were estimated through the micro-costing method, which implied identifying healthcare resources, their quantities, utilization rates and unit costs for each perspective. These procedures allow us to have rigorous and well-founded estimates for our model. Finally, our budget impact model included sensitivity and scenario analyses to evaluate the robustness of the results to variations of the main parameters of the model.

The present study has limitations. First, our budget impact model only considers the FSL reduction in the number of clinically relevant hypoglycemic events as a unique health benefit. The pivotal study also provided information about other FSL health benefits, such as the total time reduction in hypoglycemia or non-severe hypoglycemic events. Notably, reducing non-severe hypoglycemic events could bring additional health and financial benefits. Parekh et al. [40] reported for the case of Spain that non-severe hypoglycemia events represent approximately 55% of the total cost of insulin-related hypoglycemia. This limitation implies that the financial benefits for the third-party payer derived from the FSL coverage are conservative. Second, in our analysis we assumed a 100% adherence to FSL, and we considered that patients achieved the efficacy reported in the pivotal study. The effectiveness, adherence, and accuracy of FSL in Chile could differ from the efficacy reported in the clinical trial conducted in a highly controlled experimental context. Additional evidence from local real-life settings would be necessary to provide a more realistic estimation for the country. Third, although it has been reported that patients using FSL could develop cutaneous adverse events, including allergic contact dermatitis caused by the allergen isobornyl acrylate. However, since it has been published that only 0.2% of such patients require a medical follow-up [41], our model does not consider these costs. We considered that the potential inclusion of these costs would have no impact on our budget impact results. Fourth, there is still no evidence of the cost-effectiveness of the FSL at the local level. As a consequence, decision-making by third-party health payers would be limited to the budget impact results provided by this study. Finally, at the time of developing our budget impact model, the FSL effect on the reduction in glycosylated hemoglobin (HbA1c) in patients with T1DM was not widely used in other economic analyses [14–16]. However, new studies reported an association between the use of flash glucose systems with a significant reduction in HbA1c for children and adults with T1DM. Evans et al. [42] reported -through a meta-analysis involving 28,063 participants with T1DM- a significant reduction in Hba1c during a 24-month period. In addition, several studies have shown a significant association between reductions in HbA1c with total healthcare cost and diabetes management cost reductions [43,44]. Thus, the potential inclusion of this additional efficacy measure in our budget impact model would imply more favorable results for FSL.

Finally, Flash glucose monitoring has also demonstrated other health benefits in T1DM patients that usually are not considered in a budget impact analysis setting. Observational studies reported a significant improvement in patient satisfaction, quality of life (QoL) and work absenteeism in T1DM patients under flash glucose monitoring [45–47]. Moreover, reductions in HbA1c have been linked with a significant decrease in other disease event incidents related to diabetes (for instance, cardiovascular events, cataracts, and limb amputations) [48]. In other words, achieving a tight glycemic control ameliorates adverse outcomes and may reduce health expenditures usually covered by public or private insurance [49]. These benefits are of major interest considering young people as they will have a longer disease duration and could be considered in a cost-effectiveness analysis of the technology.

5. Conclusion

The incorporation of the FSL was associated with a marginal incremental cost in the public sector and with financial savings in the private sector in Chile, being the acquisition cost of the technologies the most influential factor.

Funding

This study was funded with an independent research grant from Abbott Chile (Grant number: 01/2019).

Declaration of interest

The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Reviewer disclosures

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

ORCID

Alfredo Palacios http://orcid.org/0000-0001-7684-0880
Federico Rodriguez Cairoli http://orcid.org/0000-0002-3029-4439
Carlos Balmaceda http://orcid.org/0000-0002-8381-2439
Federico Augustovski http://orcid.org/0000-0002-2914-5022
Andres Pichon-Riviere http://orcid.org/0000-0001-6052-025X
Ariel Bardach http://orcid.org/0000-0003-4437-0073

References

Papers of special note have been highlighted as either of interest (•) or of considerable interest (••) to readers.

1. Tan SY, Mei Wong JL, Sim YJ, et al. Type 1 and 2 diabetes mellitus: a review on current treatment approach and gene therapy as potential intervention. Diabetes Metab Syndr. 2019;13(1):364–372.
2. Saeedi P, Petersohn I, Salpea P, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: results from the international diabetes federation diabetes Atlas, 9th edition [Internet]. Diabetes Res Clin Pract. 2019;157:107843. .
3. Williams R, Karuranga S, Malanda B, et al. Global and regional estimates and projections of diabetes-related health expenditure: results from the international diabetes federation diabetes atlas. 9th Diabetes Res Clin Pract. 2020;162:108072.
4. Tao B, Pietropaolo M, Atkinson M, et al. Estimating the cost of type 1 diabetes in the U.S.: a propensity score matching method. PLoS One. 2010;5(7):e11501.
5. Margozzini P, Passi Á. Encuesta Nacional de Salud, ENS 2016–2017: un aporte a la planificación sanitaria y políticas públicas en Chile [Internet]. ARS MEDICA Revista de Ciencias Médicas. 2018;43(1):30–34.
6. Carrasco E, Pérez-Bravo F, Dorman J, et al. Increasing incidence of type 1 diabetes in population from Santiago of Chile: trends in a period of 18 years (1986–2003) [Internet]. Diabetes Metab Res Rev. 2006;22(1):34–37. .
7. Pathak V, Pathak NM, O'Neill CL, et al. Therapies for Type 1 Diabetes: current Scenario and future perspectives. Clin Med Insights Endocrinol Diabetes. 2019;12:1179551419844521.
8. Ministerio de Salud de Chile. Guía Clínica AUGE Diabetes Mellitus tipo 1 [Internet]. Serie Guías Clínicas, MINSAL. 2013 [cited 2021 Jun]. Available from: http://www.repositoriodigital.minsal.cl/bitstream/handle/2015/522/Diabetes-Mellitus-tipo-1-2013.pdf?sequence=1&isAllowed=y.
9. Blum A. Freestyle Libre Glucose Monitoring System [Internet]. Clin Diabetes. 2018;36(2):203–204. .
10. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, et al. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. Lancet. 2016;388(10057):2254–2263.
•Freestyle Libre efficacy study.
11. Oskarsson P, Antuna R, Geelhoed-Duijvestijn P, et al. Impact of flash glucose monitoring on hypoglycaemia in adults with type 1 diabetes managed with multiple daily injection therapy: a pre-specified subgroup analysis of the IMPACT randomised controlled trial. Diabetologia. 2018;61(3):539–550.
••Freestyle Libre efficacy study with subgroup analysis for the population considered in our study.
12. Fundación Diabetes Juvenil de Chile. Freestyle Libre [Internet]. [cited 2020 Jul 31]. Available from: http://www.diabeteschile.cl/producto/freestyle-libre-sensor.
13. Bitrán R, Escobar L, Gassibe P. After Chile's health reform: increase in coverage and access, decline in hospitalization and death rates [Internet]. Health Affairs. 2010;29(12):2161–2170. Available from.
14. Shi L, Hellmund R. Cost comparison of flash continuous glucose monitoring with self-monitoring of blood glucose in adults with type 1 or type 2 diabetes using intensive insulin—from a US private payer perspective. US Endocrinol. 2020;16(1):24
•Cost study of Freestyle Libre in patients with diabetes mellitus 1 and 2 in the US.
15. Hellmund R, Weitgasser R, Blissett D. Cost calculation for a flash glucose monitoring system for UK adults with type 1 diabetes mellitus receiving intensive insulin treatment. Diabetes Res Clin Pract. 2018;138:193–200.
•Cost study of Freestyle Libre in patients with diabetes mellitus 1 in the UK.
16. Oyagüez I, Merino-Torres JF, Brito M, et al. Cost analysis of the flash monitoring system (FreeStyle Libre 2) in adults with type 1 diabetes mellitus. BMJ Open Diabetes Res Care. Internet]. 2020;8. Available from.;(1):e001330. http://dx.doi.org/10.1136/bmjdrc-2020-001330
•Cost study of Freestyle Libre in patients with diabetes mellitus 1 in Spain.
17. Bilir SP, Hellmund R, Wehler B, et al. Cost-effectiveness analysis of a flash glucose monitoring system for patients with type 1 diabetes receiving intensive insulin treatment in Sweden. Eur Endocrinol. 2018;14(2):73–79.
••Cost-effectiveness study of Freestyle Libre in patients with diabetes mellitus 1 Sweden.
18. Healthcare Improvement Scotland, What is the clinical and cost effectiveness of Freestyle Libre® flash glucose monitoring for patients with diabetes mellitus treated with intensive insulin therapy? [Internet]. [cited 2022 May 3]. Available from: https://shtg.scot/media/1799/freestyle-libre-flash-glucose-monitoring-shtg-evidence-note-81-endocrinology-and-diab.pdf.
19. Zhao X, Ming J, Qu S, et al. Cost-effectiveness of flash glucose monitoring for the management of patients with type 1 and patients with Type 2 diabetes in China. Diabetes Ther. 2021;12(12):3079–3092.
20. Gil-Ibáñez MT, Aispuru GR. Cost-effectiveness analysis of glycaemic control of a glucose monitoring system (FreeStyle Libre®) for patients with type 1 diabetes in primary health care of Burgos. Enferm Clin. 2020;30(2):82–88.
21. Bilir SP, Li H, Wehler EA, et al. Cost effectiveness analysis of a flash glucose monitoring system for type 1 diabetes (T1DM) patients receiving intensive insulin treatment in Europe and Australia [Internet]. Value Health. 2016;19(7):A697–A698. Available from.
22. Blissett R, Blissett D, Levrat-Guillen F, et al. FreeStyle libre flash glucose monitoring system for people with type 1 diabetes in the UK: a budget impact analysis [Internet]. BMJ Open Diabetes Res Care. 2022;10(2):e002580. Available from.
23. World Bank, Official exchange rate (LCU per US$, period average) - Chile [Internet] . [cited 2021 Jul 16]. cited: https://data.worldbank.org/indicator/PA.NUS.FCRF?locations=CL.
24. Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis-principles of good practice: report of the ISPOR 2012 budget impact analysis good practice II task force. Value Health. 2014;17(1):5–14.
25. Ministerio de Salud de Chile, Estudio de Verificación del Costo Esperado Individual Promedio por Beneficiario del Conjunto Priorizado de Problemas de Salud con Garantías Explicitas. 2018; Available from: http://www.biblioteca.digital.gob.cl/handle/123456789/2328.
•Healthcare costs study in Chile.
26. NICE UK, Overview | FreeStyle Libre for glucose monitoring | Advice . [cited 2020 Jul 31]; Available from: https://www.nice.org.uk/advice/mib110.
27. Diabetes UK. NHS to provide flash glucose monitoring for people with Type 1 diabetes [Internet]. 2018. Available from: https://www.diabetes.org.uk/about_us/news/flash-on-nhs.
28. Instituto de Estadísticas de Chile, . [cited 2020 Jul 31]. Available from: https://www.ine.cl/estadisticas/.
29. Munoz CE, Weinstock RS, Brown TD, et al. Women and the American Diabetes Association. Diabetes. 2021;70(8):1638–1639.
30. Khunti K, Alsifri S, Aronson R, et al. Rates and predictors of hypoglycaemia in 27 585 people from 24 countries with insulin-treated

type 1 and type 2 diabetes: the global HAT study. Diabetes Obes Metab. 2016;18(9):907–915.
31. Tomky D. Detection, prevention, and treatment of hypoglycemia in the hospital [Internet]. Diabetes Spectr. 2005;18(1):39–44. =.
32. Veronese G, Marchesini G, Forlani G, et al. Costs associated with emergency care and hospitalization for severe hypoglycemia [Internet]. Nutr Metab Cardiovasc Dis. 2016;26(4):345–351.
33. Heller SR, Frier BM, Hersløv ML, et al. Severe hypoglycaemia in adults with insulin-treated diabetes: impact on healthcare resources. Diabet Med. 2016;33(4):471–477.
••Impact of severe hypoglycaemia events on healthcare utilization considered in our budget impact model.
34. Ministerio de Salud de Chile. Garantías Explícitas en Salud (GES) [Internet]. MINSAL. 2019 [cited 2021 Jun]. Available from: http://www.supersalud.gob.cl/difusion/665/w3-propertyvalue-1962.html.
•Description of the health benefits package in Chile.
35. Pichon-Riviere A, Drummond M, Martí SG, et al. Aplicación de la evidencia económica en la evaluación de tecnologías sanitarias y la toma de decisiones sobre asignación de recursos sanitarios en América Latina [Internet]. 2021 [cited 2021 Jun]. Available from: https://www.argentina.gob.ar/sites/default/files/nt-consideraciones-hta-la-2021.pdf.
••High budget impact threshold for Chile considered in our budget impact model.
36. Nuijten MJC, Mittendorf T, Persson U. Practical issues in handling data input and uncertainty in a budget impact analysis [Internet]. Eur J Health Econ. 2011;12(3):231–241. Available from.
37. McCabe C, Paulden M, Awotwe I, et al. One-way sensitivity analysis for probabilistic cost-effectiveness analysis: conditional expected incremental net benefit [Internet]. PharmacoEconomics. 2020;38(2):135–141.
38. American Diabetes Association. Standards of medical care in diabetes 2017. Diabetes Care [Internet]. 2017;40. Available from: https://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf.
39. National Clinical Guideline Centre (UK). Type 1 diabetes in adults: diagnosis and management. London: National Institute for Health and Care Excellence (UK); 2015.
40. Parekh W, Hoskins N, Baker-Knight J, et al. The economic burden of insulin-related hypoglycemia in Spain. Diabetes Ther. 2017;8(4):899–913.
41. Pyl J, Dendooven E, Van Eekelen I, et al. Prevalence and prevention of contact dermatitis caused by FreeStyle Libre: a monocentric experience. Diabetes Care. 2020;43(4):918–920.
42. Evans M, Welsh Z, Seibold A. Reductions in HbA1c with flash glucose monitoring are sustained for up to 24 Months: a meta-analysis of 75 real-world observational studies. Diabetes Ther. 2022;13(6):1175–1185.
43. Lage MJ, Boye KS. The relationship between HbA1c reduction and healthcare costs among patients with type 2 diabetes: evidence from a U.S. claims database. Curr Med Res Opin. Internet]. [cited 2022 Jul 5];36. Available from:: https://pubmed.ncbi.nlm.nih.gov/32643451/
44. Boye KS, Lage MJ, Thieu VT. The association between Hba1c and 1-year diabetes-related medical costs: a retrospective claims database analysis. Diabetes Ther. 2022;13(2):367–377.
45. Jiménez-Sahagún R, Gómez Hoyos E, Díaz Soto G, et al. Impact of flash glucose monitoring on quality of life and glycaemic control parameters in adults with type 1 diabetes mellitus⋆. Endocrinol Diabetes Nutr (Engl Ed). 2022;69. 345–353.
46. Lameijer A, Fokkert MJ, Edens MA, et al. Two-year use of flash glucose monitoring is associated with sustained improvement of glycemic control and quality of life (FLARE-NL-6). BMJ Open Diabetes Res Care. Internet]. 2021;9(1):e002124. Available from: http://dx.doi.org/10.1136/bmjdrc-2021-002124
47. Charleer S, De Block C, Van Huffel L, et al. Quality of life and glucose control after 1 year of nationwide reimbursement of intermittently Scanned continuous glucose monitoring in adults living with type 1 diabetes (FUTURE): a prospective observational real-world cohort study. Diabetes Care. 2020;43(2):389–397.
48. Tian J, Ohkuma T, Cooper M, et al. Effects of intensive glycemic control on clinical outcomes among patients with type 2 diabetes with different levels of cardiovascular risk and hemoglobin A in the ADVANCE Trial. Diabetes Care. 2020;43(6):1293–1299.
49. Caturano A, Galiero R, Pafundi PC, et al. Does a strict glycemic control during acute coronary syndrome play a cardioprotective effect? Pathophysiology and clinical evidence. Diabetes Res Clin Pract. 2021;178:108959.